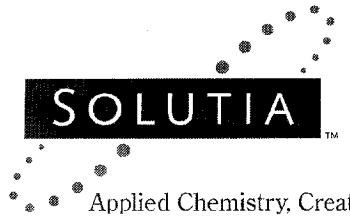
201-14542



Solutia Inc
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St. Louis, Missouri 63166-6760
Tel 314-674-1000

June 11, 2003

Acting Administrator
US Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program

In re: HPV Challenge Program – Response to EPA Comments: SN 162
Di-C7-C9-Branched and Linear Alkyl Ester (97 Adipate)
CAS Number 68515-75-3

Dear Madame/Sir:

I am pleased to forward to you our response to EPA's comments received on our referenced HPV submission, which you will find attached. In consideration of these comments, Solutia Inc. (Registration) has modified our Test Plan and Robust Summary Dossier originally submitted. Thus, I am pleased to forward to you under cover of this letter a diskette containing our Revised Test Plan and Revised Robust Summary for this HPV chemical. An electronic submission to the EPA website, containing the above information, will be made as of this date, as well.

Please contact me directly (314-674-8815) should there be any further questions related to this submission.

Sincerely,

Frederick R. Johannsen
HPV Coordinator

Attachment

Solutia Inc. - Response to EPA Comments (SN 162) on Di-C7-C9 Branched and Linear Alkyl Ester (97 Adipate) (CAS No. 68515-75-3)

Comments Regarding Test Plan

1. Physicochemical Properties

a. "…needs to measure vapor pressure at ambient temperature…"

The study reporting Vapor Pressure was a calculation based on the model of Clapeyron/Antoine. Vapor Pressure at ambient temperature has been calculated and replaces the original value in the Revised Robust Summary. We have also clarified that this value was an estimated value, and have included the reference to the methodology used. As EPA guidance is to provide measured data if an estimated value is above 1x10E5 Pa/7.5x10E-8 mm Hg (as is the case here), we will complete a Vapor Pressure assay at ambient temperature.

b. "…provide details on the boiling point experiment…"

The Boiling Point value originally reported also was derived from use of the same methodology employed for Vapor Pressure. Thus, we have recalculated the boiling point under ambient conditions and have replaced the initial value in a Revised Robust Summary for Boiling Point. As with the Vapor Pressure, we have added information as to method used and reference.

2.Environmental Fate

a. "…needs to provide estimated data for indirect photolysis in the atmosphere"; "…provide information…whether the compound absorbs at >290 nm."

We have run an AOPWIN estimate of indirect photolysis and have added those results to a Revised Robust Summary for this endpoint. We have also added additional information on direct photolysis in the Revised Test Plan.

b. "Biodegradation testing is also needed as the submitted data do not address the SIDS ready biodegradation endpoint."

We agree with the reviewer that the Ultimate Biodegradation Study summarized in this dossier does not meet the SIDS Ready Biodegradability endpoint. Thus, we have modified the Revised Test Plan to eliminate any reference to "ready or readily" biodegradable, to avoid unnecessary confusion. However, we believe that OECD Guideline # 302 (Ultimate Biodegradation) studies ARE listed in "Appendix A. Screening Information Data Set (SIDS)" as found in EPA's "OPPT Guidance Document entitled Determining the Adequacy of Existing Data (2/10/99)" which are to be used as guidance for the HPV Program. We further point to the example on page 15 of EPA's OPPTS Guidance Document entitled "Draft Guidance on Developing Robust Summaries" for HPV submissions, where EPA specifically used SCAS testing (OECD # 302) as an example. Therefore, Solutia believes this Ultimate Biodegradation test, consistent with OECD # 302, is sufficient information to meet this HPV Endpoint. No additional testing is planned.

3. Health Effects

a. "….a missing summary for one genetic toxicity study needs to be added and some deficiencies in submitted summaries need to be addressed."

We have added a Robust Summary for the gene toxicity study referenced and addressed other additions as outlined below.

b. "…needs to address an inconsistency between the high dose levels …and the robust summary."

We thank the reviewer for pointing this inconsistency out and have taken measures to bring values into alignment between Revised Test Plan and Revised Robust Summary.

4. Ecological Effects

a. " …results for acute toxicity testing in fish, daphnia, and green algae are not adequate because they were tested above the water solubility limit and the test concentrations were not measured."

Solutia has reviewed the comments provided by EPA and still maintains that the acute fish, daphnia and green algae studies submitted with 97 Adipate meet requirements set out for HPV data submissions. Thus, they are sufficient to address these HPV Endpoints. We remind the reviewer that the comment as to need for measured test concentrations is NOT an HPV requirement. We refer the reviewer to EPA's OPPT Guidance Document entitled "Determining the Adequacy of Existing Data", section 6.3 Ecotoxicity Tests, fifth bullet, where guidance specifically states that "measured concentrations preferred over nominal concentrations"; hence, nominal concentrations are still acceptable. The fact that test solutions exceeded the water solubility of 97 Adipate should NOT negate the utility of these studies to assess the acute aquatic toxicity of this chemical, as we described in the Test Plan and Robust Summaries. In each study performed, the lowest test concentrations used reflected a saturated aqueous test concentration, as the solubility limit was exceeded. At those test concentrations, no deaths/effects were observed to negatively affect the outcome of the biological response. Therefore, it is scientifically valid to conclude that up to the limits of aqueous solubility, no toxicological effects were seen with 97 Adipate. Effects observed above levels of aqueous solubility are of no relevance to ecological risk. We note that EPA has accepted (recent example: 1,3,5-Trioxane; CAS no. 110-83-3) such studies in previous HPV submissions. Similar studies (example: n-Butyl Acetate) have also been accepted internationally in the OECD SIDS test program. Thus, Solutia believes the Agency should accept these studies as adequate to fulfill these HPV Endpoints. No further testing of these HPV Endpoints is planned.

Specific Comments related to the Robust Summaries

a. General comments – We have reviewed and modified each Robust Summary, as needed, to clearly identify the test substance used for each study.
b. Physicochemical Properties – see comments above
c. Environmental Fate – Further discussion of low water solubility re: hydrolysis has been added to the Revised Robust Summary
d. Health Effects – Specific tissues/organs making up the "40 tissues" cited in the Repeated Dose Robust Summary have been added.
e. Developmental Toxicity – Further documentation of the results of maternal and fetal body weights and in rudimentary structures has been added to the Revised Robust Summary.

6/010/03